

WHAT IS CLAIMED IS:

1 1. An apparatus for collection and lateral flow chromatography of an  
2 oral fluid, the apparatus comprising:  
3 a lateral flow chromatography strip including a receiving area;  
4 a capillary matrix having a surface; and  
5 a bite portion coupled to the capillary matrix and insertable between  
6 teeth of a subject to position the surface of the capillary matrix for receiving an oral fluid of  
7 the subject, the capillary matrix being in communication with the lateral flow  
8 chromatography strip to wick up and deliver the received oral fluid to the receiving area of  
9 the lateral flow chromatography strip.

1 2. The apparatus of claim 1, wherein the bite portion positions the  
2 capillary matrix in a buccal space of the subject.

1 3. The apparatus of claim 1, wherein the capillary matrix is sheet-like in  
2 shape and the bite portion comprises a bite plate disposed substantially perpendicular to the  
3 capillary matrix.

1 4. The apparatus of claim 1, wherein the bite portion comprises textured  
2 surfaces for contacting the teeth.

1 5. The apparatus of claim 1, wherein the bite portion comprises a saliva-  
2 stimulating substance.

1 6. The apparatus of claim 5, wherein the saliva-stimulating substance is  
2 selected from the group consisting of citric acid, tartaric acid, fumaric acid, ascorbic acid,  
3 malic acid, salt, fructose, glucose, sucrose, and artificial sweetener, and aromatic compound.

1 7. The apparatus of claim 1, wherein the bite portion is insertable  
2 between the teeth of the subject to contact a tongue of the subject.

1 8. The apparatus of claim 1, wherein the bite portion is insertable  
2 between the teeth in proximity to the tongue of the subject

1 9. The apparatus of claim 1, further comprising a housing having a  
2 cavity in which the lateral flow chromatography strip is at least partially disposed.

1 10. The apparatus of claim 9, wherein the housing includes at least one  
2 inspection site providing visual inspection of reagents at selected sites on the lateral flow  
3 chromatography strip.

1 11. The apparatus of claim 9, wherein the housing is connected to the bite  
2 portion.

1 12. The apparatus of claim 9, wherein the housing is connected to the  
2 capillary matrix.

1 13. The apparatus of claim 9, wherein the capillary matrix is insertable  
2 partially into the cavity of the housing which acts as a handle for inserting the capillary  
3 matrix into an oral cavity of the subject.

1 14. The apparatus of claim 1, wherein the lateral flow chromatography  
2 strip includes lateral flow chromatography reagents.

1 15. The apparatus of claim 1, further comprising a conjugate strip coupled  
2 between the capillary matrix and the lateral flow chromatography strip and including lateral  
3 flow chromatography reagents.

1 16. The apparatus of claim 1, further comprising a blocking strip coupled  
2 between the capillary matrix and the lateral flow chromatography strip and including a  
3 detergent.

1 17. The apparatus of claim 16, wherein the blocking strip further includes  
2 a buffer.

1 18. The apparatus of claim 1, further comprising an absorbent material  
2 coupled near an end of the lateral flow chromatography strip opposite from the capillary  
3 matrix.

1 19. The apparatus of claim 1, further comprising a cover for protecting the  
2 capillary matrix.

1 20. The apparatus of claim 1, wherein saturation of the capillary matrix  
2 with an oral fluid does not substantially alter the morphology of said capillary matrix.

1 21. The apparatus of claim 20, wherein saturation of the capillary matrix  
2 with an oral fluid does not substantially alter the average pore size of said capillary matrix.

1 22. The apparatus of claim 20, wherein saturation of the capillary matrix  
2 with an oral fluid does not substantially alter the void volume of said capillary matrix.

1 23. The apparatus of claim 20, wherein the capillary matrix has an  
2 average pore size ranging from about 40  $\mu\text{m}$  to about 250  $\mu\text{m}$ .

1 24. The apparatus of claim 20, wherein the capillary matrix has a void  
2 volume of less than about 60  $\mu\text{L}$ .

1 25. The apparatus of claim 1, wherein the capillary matrix comprises a  
2 plastic.

1 26. The apparatus of claim 25, wherein the capillary matrix comprises a  
2 plastic selected from the group consisting of a polyethylene (PE), a polyester, a polystyrene,  
3 a high density polyethylene (HDPE), an ultra-high molecular weight polyethylene (UHMW),  
4 a polypropylene (PP), a polyvinylidene fluoride (PVDF), a polytetrafluoroethylene (PTFE),  
5 a nylon 6 (N6), and a polyethersulfone (PES).

1 27. The apparatus of claim 25, wherein the plastic is hydrophilic or  
2 treated to be hydrophilic.

1 28. The apparatus of claim 1, wherein the capillary matrix, when  
2 contacted to an oral mucosa takes up oral fluid from the subject and releases the oral fluid to  
3 the receiving area of the lateral flow chromatography strip in under about 2 minutes.

1           29.    The apparatus of claim 28, wherein the capillary matrix, when  
2   contacted to an oral mucosa takes up oral fluid from the subject and releases the oral fluid to  
3   the receiving area of the lateral flow chromatography strip in under about 30 seconds.

1           30.    The apparatus of claim 28, wherein the capillary matrix is saturated  
2   with oral fluid in under about 1 minute.

1           31.    The apparatus of claim 1, wherein the capillary matrix is saturated by  
2   less than about 300  $\mu$ L of oral fluid

1           32.    The apparatus of claim 31, wherein the capillary matrix is saturated by  
2   less than about 100  $\mu$ L of oral fluid.

1           33.    The apparatus of claim 1, wherein the capillary matrix releases the  
2   oral fluid to the receiving area of the lateral flow chromatography strip without compression  
3   of the capillary matrix.

1           34.    The apparatus of claim 33, wherein sufficient oral fluid is released to  
2   saturate the receiving area.

1           35.    An apparatus for collection and lateral flow chromatography of an  
2   oral fluid, the apparatus comprising:  
3                   a lateral flow chromatography strip including a receiving area;  
4                   a bite portion insertable between teeth of a subject; and  
5                   collection means coupled to the bite portion to contact an oral mucosa  
6   of the subject for receiving oral fluid of the subject, and in communication with the lateral  
7   flow chromatography strip for wicking up and delivering the received oral fluid to the  
8   receiving area of the lateral flow chromatography strip.

1           36.    The apparatus of claim 35, wherein the bite portion comprises a  
2   saliva-stimulating substance. *Q*

1           37.    The apparatus of claim 35, wherein the bite portion is insertable  
2   between the teeth of the subject to contact a tongue of the subject.

1 38. The apparatus of claim 35, wherein the bite portion is insertable  
2 between the teeth of the subject in proximity to a tongue of the subject.

1 39. The apparatus of claim 35, further comprising conjugate means,  
2 coupled between the collection means and the lateral flow chromatography strip, for  
3 providing lateral flow chromatography reagents.

1 40. The apparatus of claim 35, further comprising adjusting means,  
2 coupled between the collection means and the lateral flow chromatography strip, for  
3 adjusting a pH of the received oral fluid.

1 41. The apparatus of claim 35, further comprising blocking means,  
2 coupled between the collection means and the lateral flow chromatography strip, for  
3 blocking unwanted substances from the collection means.

1 42. The apparatus of claim 35, further comprising blocking means,  
2 coupled between the collection means and the lateral flow chromatography strip, for  
3 preventing backflow of reagents or oral fluid from the lateral flow chromatography strip to  
4 the collection means.

1 43. The apparatus of claim 35, further comprising absorbent means  
2 coupled to the lateral flow chromatography strip for receiving the oral fluid from the  
3 collection means to prevent backflow thereof to the collection means.

1 44. The apparatus of claim 35, wherein the bite portion is held in place by  
2 occlusal force of the teeth to position the collection means for receiving the oral fluid.

1 45. A method of detecting an analyte in oral fluid of a subject, said  
2 method comprising:  
3 inserting the apparatus of claim 1 or claim 35 into the oral cavity of  
4 said subject such that said bite portion is held between the teeth of said subject;  
5 retaining said apparatus in said oral cavity until an oral fluid sample is  
6 collected; and  
7 reading the presence or absence of said analyte from an indicator  
8 region on said apparatus.

1 46. A kit for detection of an analyte in oral fluid of a subject, said kit  
2 comprising a container containing the apparatus of claim 1 or the apparatus of claim 35.

1 47. The kit of claim 46, further comprising instructional materials  
2 describing the use of said apparatus for detecting said analyte.

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